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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/586,941 06/02/00 KUNZLER

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EXAMINER

ROBERTSON, J	
ART UNIT	PAPER NUMBER

1712
DATE MAILED:

6
07/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/586,941

Applicant(s)

KUNZLER ET AL.

Examiner

Jeffrey B. Robertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 5, lines 14 and 15, P(acrylamide-co-AA) appears twice in the list of wetting agents. On page 3, in the second and third lines under (b) of SUMMARY OF THE INVENTION, applicants have written "(meth)acrylic" and "meth(acrylic)". On page 12, line 25, applicants have not defined "proton donating solubes".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 8, 9, and 12-20 are rejected under 35 U.S.C. 112, first paragraph.

For claim 1 the specification, while being enabling for wetting agents including polymers and copolymers of methacrylic acid, P(vinylpyrrolidinone(VP)-co-acrylic acid(AA)), P(methylvinylether-alt-maleic acid), P(acrylic acid-graft-ethyleneoxide), P(acrylic acid-co-methacrylic acid), P(acrylamide-co-AA), P(AA-co-maleic), and P(butadiene-maleic acid), does not reasonably provide enablement for proton-donating wetting agent. On pages 3 and 5, applicants set forth appropriate wetting agents, however the term "proton-donating wetting agent" in claim 1 is not defined in the specification.

For claims 3 and 8, the specification, while being enabling for wetting agents including polymers and copolymers of methacrylic acid, P(vinylpyrrolidinone(VP)-co-acrylic acid(AA)), P(methylvinylether-alt-maleic acid), P(acrylic acid-graft-ethyleneoxide), P(acrylic acid-co-methacrylic acid), P(acrylamide-co-AA), P(AA-co-maleic), and P(butadiene-maleic acid), does not reasonably provide enablement for wetting agents including sulfonic acids, fumaric acids, anhydrides, and vinyl alcohols. The specification, on page 12, lines 24-28, sets forth solvents that solubilize these compounds, but the specification does not state that these compounds are useful as wetting agents.

For claims 4 and 9, the specification, while being enabling for 5 to 50 percent by weight of one or more silicone macromonomers, does not reasonably provide enablement for 5 to 75 percent by weight of one or more silicone macromonomers. On page 11, in the last paragraph, applicants have set forth that the silicone macromonomer is present in 5 to 50 weight percent of the composition, not 5 to 75 weight percent of the composition.

For claims 12 and 13 the specification, while being enabling for an acid content of at least 40 mole percent, does not reasonably provide enablement for an acid content of at least 30 mole percent. On page 3, lines 25-27 applicant require the acid content to be at least 40 mole percent.

For claim 19 the specification, while being enabling for providing a medical device formed from a monomer mixture comprising a hydrophilic monomer and a silicone-containing monomer, does not reasonably provide enablement for providing a

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medical device comprising a silicone-containing monomer and at least one other monomer. On page 3, lines 17 and 18, applicants set forth that the medical device is formed from a monomer mixture comprising a hydrophilic monomer and a silicone-containing monomer. Applicants do not set forth that the medical device may contain the silicone-containing monomer and hydrophilic monomer in the original monomer forms.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 8, the Markush group in claim 7, from which claim 8 depends, requires that the wetting agent be polymer or copolymer of methacrylic acid. Since claim 8 must further limit claim 7, it is not understood how the compounds set forth in claim 8 are polymers or copolymers of methacrylic acid.

For claims 12 and 13, claim 12 recites the limitation "said polymer" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no polymer mentioned in claim 1.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-6, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (U.S. Patent No. 5,712,327).

For claims 1, 3, and 15-18, in column 3, lines 30-64, Chang et al. teaches that a hydrophilic soft gas permeable contact lens is made by polymerizing a silicone containing monomer and a hydrophilic monomer. In column 4, lines 46-63, Chang et al. teaches that the lens surface is modified with a polyol that may contain a glyceryl methacrylate. The reaction is intended to increase the hydroxy acrylic monomer units at the surface through transesterification. For claims 4-6, in column 6, lines 1-10, Chang et al. teaches that contact lens is made by using 36% of a silicone containing monomer, and 59% by weight of dimethylacrylamide.

8. Claims 1-3 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai et al. (U.S. Patent No. 5,726,733).

For claims 1, and 15-18, in column 3, lines 9-25, Lai et al. teaches that contact lenses are treated to improve the hydrophilicity of the lens. Lai et al. discloses that the lenses are copolymers of a silicone containing monomer and a hydrophilic monomer. For claims 2 and 3, in column 1, lines 47-61, Lai et al. teaches that the contact lens is

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treated with a hydrophilic monomer such as methacrylic acid. In column 2, lines 11-20, Lai et al. teaches that the surfaces of the lenses are treated with an aqueous solution of the treating agent.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. as applied to claim 1 above, and further in view of Kunzler et al. (U.S. Patent No. 5,710,302).

Lai et al. teaches the limitations of claim 1 as outlined above. Lai et al. fails to teach that the contact lenses have the specific compositions outlined in claims 4-6.

Kunzler et al. teaches silicone hydrogel contact lenses that contain from about 10 to about 89 weight percent of a silicone containing monomer and from about 10 to 70 weight percent hydrophilic monomeric units in column 2, lines 38-47. For claims 5 and 6, Kunzler et al. teaches that the hydrophilic monomer is dimethyl acrylamide in column 12, lines 5-11.

Lai et al. and Kunzler et al. are analogous art in that they are from the same field of endeavor, namely, silicone hydrogel contact lenses. It would have been obvious to one of ordinary skill in the art at the time of the invention to use treat the silicone hydrogel lenses of Kunzler et al. with the method of Lai et al. The motivation would

have been that Lai et al. states that the method of treating lenses applies to silicone-containing hydrogel lenses, but fails to teach a specific lens. One of ordinary skill in the art would have turned to Kunzler et al. for specific silicone-containing hydrogel lenses.

11. Claims 1-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunzler et al. (U.S. Patent No. 5,710,302) in view of Bowers et al. (U.S. Patent No. 5,705,583).

For claims 1, 4-7, 9-11, and 15-18, Kunzler et al. teaches silicone hydrogel contact lenses that contain from about 10 to about 89 weight percent of a silicone containing monomer and from about 10 to 70 weight percent hydrophilic monomeric units in column 2, lines 38-47. For claims 5 and 6, Kunzler et al. teaches that the hydrophilic monomer is dimethyl acrylamide in column 12, lines 5-11. Kunzler et al. fails to teach that the surface of the contact lens is contacted with a wetting agent.

Bowers et al. teaches a process of binding a polymer to a surface by covalent bonding, specifically to render the surfaces biocompatible in column 1, lines 1-42. The polymer is specifically useful when surfaces come into contact with protein-containing solutions to discourage protein adsorption. In column 31, lines 24-31, Bowers et al. lists medical devices that would benefit from this coating such as contact lenses. In column 28, line 58, through column 29, line 5, Bowers et al. teaches that up to 25% of the polymer is made up from monomers that bind to a polymer surface covalently, and that up to 95% of the polymer is made up of "diluent comonomers". For claims 1-3, 7, and 8,

in column 22, lines 38-39, Bowers et al. teaches that methacrylic acid is a suitable monomer that will bind to a surface covalently.

For claims 12 and 13, Bowers et al. fails to teach an acid content of at least 30 or 40 mole percent. However, applicants have shown no criticality to this variable. The acid content of the polymer would be a result effective variable. A result effective variable is determined according to the desired properties of the resulting composition and would be obvious to one of ordinary skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Bowers et al. and Kunzler et al. are analogous art because they both are directed to improving medical devices such as contact lenses in compatibility with the eye and durability against fluids produced by the eye. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the polymer coatings of Bowers et al. on the contact lenses of Kunzler et al. The motivation would have been that the contact lenses of Kunzler et al. are subject to protein deposits commonly known to occur on contact lenses. The coatings of Bowers et al. would have been applied to try to overcome this deposit formation.

Allowable Subject Matter

12. Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. Claims 19 and 20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action.

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14. The following is a statement of reasons for the indication of allowable subject matter: For claims 14 and 19, none of the above cited prior art teaches or suggests the specific polymer combinations for use as a wetting agent or coating in medical devices.


Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Merrill (U.S. Patent No. 3,916,033), Gesser et al. (U.S. Patent No. 3,925,178), Enns et al. (U.S. Patent No. 5,779,943), and Nicolson et al. (U.S. Patent No. 5,789,461) are being cited because they all relate to the surface treatment of contact lenses to improve hydrophilicity. However, each of these patents requires the use of a surface oxidation treatment step, or the addition of a coupling agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (703) 306-5929. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

JBR 
July 24, 2001



Robert Dawson
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